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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/549,992	06/09/2006	Arturo Talavera Coronel	LEXSAP35	1026

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EXAMINER	
OGUNBIYI, OLUWATOSIN A	
ART UNIT	PAPER NUMBER
1645	

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01/28/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/549,992	TALAVERA CORONEL ET AL.	
	Examiner	Art Unit	
	Oluwatosin Ogunbiyi	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26* is/are rejected.

7)☒ Claim(s) *1,2,7 and 26* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 September 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-26 are pending and are under examination.

Priority

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Drawings

New corrected drawings are required in this application because it is impossible to distinguish between each of the data points depicted in fig. 1, fig. 2 and fig. 4b as it is not clear what the x- axis represents for fig. 1 and 2 and 4b and it is not clear what the y axis represents in fig. 2 and fig. 4b. Further, the word 'days' is misspelled on the graph for fig. 4a.

The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Specification

The disclosure is objected to because of the following informalities: the word 'whole' is misspelled as 'hole' in several places in the application. See for example p. 6,7 and 9.

Appropriate correction is required.

Information Disclosure Statement

An information disclosure statement has not been filed.

Claim Objections

Claims 1,2,7 and 25 are objected to because of the following informalities: '*Vibrio cholera*' should be '*Vibrio cholerae*' in claim 1. 'Cholera' and '*Vibrio cholerae*' is misspelled in claim 25. Appropriate correction is required.

Also, *Vibrio cholerae* should be italicized where it appears in the claims.

Claim Rejections - 35 USC 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6,13,14,15,17,19,21,24,25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mekalanos et al. US 6,203,799, March 20, 2001 in view of Remington: The Science and Practice of Pharmacy, the 20th edition, 2000, chapters 45 and 46.

The claims are drawn to a vaccine composition for cholera comprising a. inactivated cells of *Vibrio cholerae*; b. an agglutinant; c. a lubricant; d. a coating substance; e. a filling substance: and f. a disintegrating substance.

Mekalanos et al teaches a composition comprising killed (inactivated) cells of *Vibrio cholerae* in a tablet form (column 28 claim 23 and column 11 lines 21 -25). Said inactivated cells are attenuated (mutant) strains of *Vibrio cholerae* (column 28 claim 23). Said vaccine composition comprises inactivated cells belonging to serum group 0139 or serum group O1 (column 4 lines 30-39 and lines 62-67 to column 5 lines 1-4). Said composition further comprises El Tor type cells (column 4 lines 30-39 and lines 62-67 to column 5 lines 1-4) and said inactivated cells belong to the Ogawa or Inaba serum type (column 4 lines 30-39, column 6 table 2). Mekalanos teaches that said composition is formed in a tablet which is an oral administrating unit comprising inactivated whole cells of *Vibrio Cholerae* for oral administration (column 28 claim 23 and column 11 lines 21 -25).

Mekalanos does not teach table ingredients such as agglutinant, lubricant, coating substance, filling substance and disintegrating substance.

Remington teaches orals dosage forms such as tablets and methods of making such tablets. Remington teaches ingredients that are commonly and routinely used to make tablets such as agglutinants (gelatin, carboxymethylcellulose and crospovidone, chapter 45 p. 860 under Binders and Disintegrants); lubricant (talc, magnesium stearate, silicon dioxide, talc, carboxymethyl starch (carboxymethyl cellulose or sodium lauryl sulfate in combination with starch, chapter 45 p. 861 under lubricants and p.862 under glidants and under disintegrants); coating substance (cellulose acetate phthalate, shellac (lacquer), titanium dioxide, chapter 46 p. 895 and 896); filling substances (lactose or cornstarch, chapter 45 p. 860 under Diluents and Binders) and disintegrating substances (cornstarch, micro-crystalline cellulose and croscarmelose chapter 45 p. 860-861 under Diluents and Binders and 862 under disintegrants). Remington teaches ranges of the amounts of above tablet components e.g. agglutinants varies from 5% or varies from 10%-20%; lubricants below 1% to as high as 5%; coating substances; filling substances varies from 5% or varies from 10%-20% for cornstarch; disintegrating substances varies from 5 to 15%).

It would have been prima facie obvious to one of ordinary skill in the art at the time the instant invention was made to include all ingredients for making tablets in the tablet composition of Mekalanos et al as taught by Remington resulting in the instant invention with a reasonable expectation of success. This is because Remington teaches orals dosage forms such as tablets and methods of making such tablet and teaches the ingredients and their amounts that are commonly and routinely used to make tablets such as agglutinants, lubricant, coating substance, filling substance and disintegrating substances.

Claims 13, 14, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mekalanos et al. US 6,203,799, March 20, 2001 and Remington: The Science and Practice of Pharmacy, the 20th edition, 2000, chapters 45 and 46 as applied to claims 1-6,13,14,15,17;19,21,24,25 and 26 above further in view of Feltz et al. Oct. 3, 1989 US 4,871,546.

The claims are drawn to a vaccine composition for cholera comprising a. inactivated cells of *Vibrio cholerae*; b. an agglutinant; c. a lubricant; d. a coating substance; e. a filling substance: and f. a disintegrating substance wherein the agglutinant is povidone; wherein the coating substance is cellulose diethyl phthalate.

The combination of Mekalanos and Remington is set forth supra. Said combination does not teach an agglutinant such as povidone and said combination does not teach a coating substance such as cellulose diethyl phthalate.

Feltz teaches diethyl phthalate (coating; see column 5 example 3) and povidone (column 6 example 5) as tablet components.

It would have been prima facie obvious to one of ordinary skill in the art at the time the instant invention was made to use any of the agglutinants known in the tablet making art such as povidone or use any other coating substance such as diethyl phthalate (cellulose diethyl phthalate is equivalent to diethyl phthalate absent evidence to the contrary and the instant specification does not provide a structure for cellulose diethyl phthalate) in the tablet formulation of Mekalanos and Remington as combined as taught by Feltz, thus resulting in the instant invention with a reasonable expectation of success. Further, Remington et al teaches methods of making such tablet and teaches the ingredients and the amounts of agglutinant and coating substances that are used in the art. It is obvious for one of skill in the art at the time the instant

invention was made to try to optimize these ranges and arrive at the instant ranges with a reasonable expectation of success following the teachings of Remington in chapter 45 and 46

Claims 7-12,16,18,20,22, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mekalanos et al. US 6,203,799, March 20, 2001 and Remington: The Science and Practice of Pharmacy, the 20th edition, 2000, chapters 45 and 46 as applied to claims 1-6,13,14,15,17,19,21,24,25 and 26 above further in view of Trach et al. The Lancet vol. 349, January 25, 1997 p.231-235.

The claims are drawn to a vaccine composition for cholera comprising a. inactivated cells of *Vibrio cholerae*; b. an agglutinant; c. a lubricant; d. a coating substance; e. a filling substance: and f. a disintegrating substance, said inactivated cells consisting of attenuated strains of *Vibrio cholerae* wherein said inactivated cells consisting of wild strains of *Vibrio cholerae*.

The combination of Mekalanos and Remington does not teach inactivated cells consisting of wild strains of *Vibrio cholerae*.

Trach et al teaches a vaccine comprising inactivated cells of wild strains of *Vibrio cholerae* (p. 232 column 1 under Vaccine and P. 235 column 1 last paragraph). Trach teaches wilds strains of O1 and O130 serum groups and El Tor and Classic biotypes and Ogawa and Inaba serum types. Trach teaches about 10^{11} cells in said vaccine ($2.5 \times 10^{10} \times 4$).

It would have been prima facie obvious to one of ordinary skill in the art to try to use wild strains of *Vibrio cholerae* (such as 10^{11} cells) in the tablet formulation of Mekalanos and Remington as combined as taught by Trach et al because Trach et al teaches a vaccine composed of wild strains of inactivated *Vibrio cholerae* in an oral vaccine, thus resulting in the instant invention with a reasonable expectation of success. Trach et al teaches that said vaccine

can confer substantial protection against cholera and thus one of skill in the art would be motivated to use such wild strains in a tablet form which form can provide ease of use and convenience to the consumer or vacinee. As to the ranges of amounts of lubricant and coating substance, filling substance and disintegrating substance as disclosed in the claims, Remington teaches ranges of the amounts of these substances used in tablet formulations and various criteria for making tablet formulations (such as solubility and physicochemical characteristics) to ensure that drug-delivery goals and therapeutic efficacy of active ingredients is not diminished. Thus, it is obvious for one of skill in the art at the time the instant invention was made to try to optimize these ranges and arrive at the instant ranges with a reasonable expectation of success following the teachings of Remington in chapter 45 and 46.

Status of the Claims

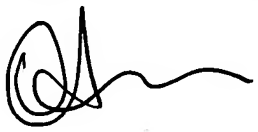
Claims 1-26 are rejected. No claims allowed. Claim 1,2,7 and 25 are objected to.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Oluwatosin Ogunbiyi whose telephone number is 571-272-0855. The

examiner can normally be reached on M-F 8:30 am - 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisory Examiner Shanon Foley can be reached on 571-272-0898.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Oluwatosin Ogunbiyi

Examiner

Art Unit 1645